REMARKS

This amendment responds to the final Office Action mailed November 16, 2006. Previously, Claims 1 and 12-42 were pending. In the instant amendment, Claims 1, 12, 28 and 29 have been amended. Claims 14-17, 22, 30 and 32-35 have been canceled. After entry of the instant amendment, Claims 1 and 12-13, 18-21, 23-29, 31 and 36-42 will be pending and under consideration in the instant application.

I. AMENDMENTS TO THE CLAIMS

In the instant amendment, Claims 14-17, 22, 30 and 32-35 have been canceled without prejudice to Applicant's right to pursue the canceled subject matter in one or more related divisional, continuation and continuation-in-part patent applications.

Claim 1 has been amended to specify the mutations at amino acid positions 34 and 43, delete certain mutations and exclude certain mutations from the claimed subject matter. Claims 12 and 28 have been amended to delete certain mutations. Support for the amendments to Claim 1 can be found, in the specification, for example, at from page 6, line 23 to page 8, line 8, and at page 44, lines 6-8. Applicants respectfully submit that each of the mutations affirmatively excluded from the claims was originally described in the application as filed, for example, from page 6, line 23 to page 8, line 8, at page 44, lines 6-8, and in Tables 1-2. Accordingly, the amendment excluding these mutations is fully supported by the application as filed and presents no new matter. *See In re Johnson*, 194 U.S.P.Q. 187 (C.C.P.A. 1977) and M.P.E.P § 2173.05(i).

Applicants submit that these amendments do not introduce any new matter and are fully supported by the specification as filed. Therefore, entry and consideration thereof is respectfully requested.

II. THE OBJECTIONS TO THE CLAIM AMENDMENTS FILED AUGUST 17, 2006

The Patent Office objects to the claim amendments filed August 17, 2006, alleging that added negative limitations introduce new matter into the disclosure of the invention. Claims 32-33 reciting the negative limitation "the amino acid at position 79 is not P" are canceled and thus the objection in connection with the amendments to Claims 32-33 are moot in view of the cancellation of the claims.

The case law provides that claims can be properly amended to exclude one or more species of a genus when the specification provides a generic disclosure of the genus and

numerous species within the genus, and such amendments are not claiming new matters. *See In re Johnson*, 558 F.2d 1008 at 1019 (C.C.P.A. 1977). Here, the mutations I54V and V82A among a genus of mutations were described in the application as originally filed, for example, at page 44, lines 9-10, and in Tables 1-2. Thus, the amendments reciting the negative limitations of the mutations of I54V and V82V are supported by the application as originally filed and introduce no new matter. Accordingly, the objections to the amendments filed August 17, 2006 is respectfully requested.

III. THE REJECTION OF CLAIMS UNDER 35 U.S.C. §102(b)

A. The Rejection of Claims 1, 12, 15, 26-27, 29, 34, 36-37, 39-40 and 42 over Robinson *et al.*

Claims 1, 12, 15, 26-27, 29, 34, 36-37, 39-40 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Robinson *et al.*, 2000, *AIDS RES. & HUMAN RETROVIRUS* 16:1149-56 ("Robinson *et al.*"). The Patent Office alleges that Robinson *et al.* teaches that the E34G mutation of HIV-1 protease can be used to assess amprenavir susceptibility. Although Applicants do not agree with this rejection, to expedite the prosecution of the instant application, Applicants have amended Claim 1 by specifying that the mutation at amino acid position 34 of HIV protease is Q. Applicants respectfully submit that the rejection of Claims 1, 12, 15, 26-27, 29, 34, 36-37, 39-40 and 42 is obviated in view of the amendments to Claim 1 as Robinson *et al.* does not teach each and every element of the invention as presently claimed. Therefore, Robinson *et al.* cannot anticipate Claims 1, 12, 15, 26-27, 29, 34, 36-37, 39-40 and 42 as presently pending. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 15, 26-27, 29, 34, 36-37, 39-40 and 42 as being anticipated by Robinson *et al.* under 35 U.S.C. § 102(b) be withdrawn.

B. The Rejection of Claims 1, 12, 22, 29-30, 36 and 42 over Condra *et al.*

Claims 1, 12, 22, 29, 30, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Condra *et al.*, 1996, *J. VIROLOGY* 72(9):7532-41 ("Condra *et al.*"). Specifically, the Patent Office alleges that Condra *et al.* teaches the use of L33I, Q58E and V82F mutations of HIV-1 protease to assess amprenavir susceptibility. Although Applicants do not agree with this rejection, to expedite the prosecution of the instant application, Applicants have amended Claim 1 by (1) deleting the detection of a mutation at amino acid position 33 or 58, and (2) affirmatively excluding V82F mutation from the claim. Applicants

respectfully submit that the rejection of Claims 1, 12, 22, 29-30, 36 and 42 is obviated in view of the amendments to Claim 1 as Condra *et al.* does not teach each and every element of the invention as presently claimed. Therefore, Condra *et al.* cannot anticipate Claims 1, 12, 22, 29-30, 36 and 42 as presently pending. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990). Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 22, 29-30, 36 and 42 as being anticipated by Condra *et al.* under 35 U.S.C. § 102(b) be withdrawn.

C. The Rejection of Claims 1, 12, 17, 26-28, 32-36 and 42 over Palmer *et al.*

Claims 1, 12, 17, 26-28, 32-36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Palmer *et al.*, 1999, *AIDS* 71(2):661-67 ("Palmer *et al.*"). Specifically, the Patent Office alleges that Palmer *et al.* teaches the use of P79AS, I54T, and K43T mutations of HIV-1 protease to assess amprenavir susceptibility.

The Patent Office uses the printouts of query results from the Stanford University HIV Drug Resistance Database to show that Palmer *et al.* teaches that the K43T mutation of HIV-1 protease is associated with amprenavir resistance. However, Applicants respectfully submit that Palmer *et al.* itself teaches neither the K43T mutation nor its use in accessing amprenavir resistance. Nowhere in Palmer *et al.* is the K43T mutation even mentioned. The only mutation disclosed in Palmer *et al.* at the amino acid position 43 of HIV protease is K43N. *See* Palmer *et al.*, Table 1 at page 662.

Although Applicants do not agree with this rejection, to expedite the prosecution of the instant application, Applicants have amended Claim 1 by (1) specifying that the mutation at amino acid position 43 of HIV protease is T, (2) deleting the detection of a mutation at amino acid position 79, and (3) affirmatively excluding I54T mutation from the claim. Applicants respectfully submit that the rejection of Claims 1, 12, 17, 26-28, 32-36 and 42 is obviated in view of the amendments to Claim 1 as Palmer *et al.* does not teach each and every element of the invention as presently claimed. Therefore, Palmer *et al.* cannot anticipate Claims 1, 12, 17, 26-28, 32-36 and 42 as presently pending. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990). Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 17, 26-28, 32-36 and 42 as being anticipated by Palmer *et al.* under 35 U.S.C. § 102(b) be withdrawn.

D. The Rejection of Claims 1, 12, 13, 21 and 42 over Colonno *et al.*

Claims 1, 12, 13, 21 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Colonno *et al.*, 2000, *ANTIVIRAL THERAPY* 2000, 5 (Supplement 3):7. ("Colonno *et al.*"). Applicants respectfully traverse.

The Patent Office alleges that Colonno *et al.* teaches the use of V11I, I54T, L76V and K43T mutations of HIV-1 protease to assess amprenavir susceptibility. The Patent Office uses the printouts of query results from the Stanford University HIV Drug Resistance Database to show that Colonno *et al.* teaches these mutations and their association with amprenavir resistance. However, Applicants respectfully submit that Colonno *et al.* itself teaches neither these mutations nor their use in accessing amprenavir resistance. Applicants respectfully request the Patent Office cite the page and line number of Colonno *et al.* that teaches the use of V11I, I54T, L76V and K43T mutations of HIV-1 protease to assess amprenavir susceptibility.

Applicants respectfully submit that Colonno *et al.* does not anticipate amended Claims 1, 12, 13, 21 and 42 because Colonno *et al.* does not teach each and every element of Claims 1, 12, 13, 21 and 42 as presently amended. For instance, Colonno *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. In addition, Colonno *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Colonno *et al.* does not teach each and every element of Claims 1, 12, 13, 21 and 42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 7, 12, 13, 16 and 42 as being anticipated by Colonno *et al.* under 35 U.S.C. § 102(b) be withdrawn.

E. The Rejection of Claims 1, 12, 14, 17, 20, 36 and 42 over Kempf *et al.*

Claims 1, 12, 14, 17, 20, 36 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kempf *et al.*, 2001, *J. VIROLOGY* 75(16):7462-69 ("Kempf *et al.*"). Applicants respectfully traverse.

Applicants respectfully submit that Kempf *et al.* does not anticipate amended Claims 1, 12, 14, 17, 20, 36 and 42 because Kempf *et al.* does not teach each and every element of Claims 1, 12, 14, 17, 20, 36 and 42 as presently amended. For instance, Kempf *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1)

has an increased likelihood of having a reduced susceptibility to treatment with amprenavir. Kempf *et al.* does not teach that the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir. Thus, Kempf *et al.* does not teach each and every element of Claims 1, 12, 14, 17, 20, 36 and 42 and therefore cannot anticipate such claims. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

The Patent Office alleges that Kempf *et al.* teaches the use of L33F, K43T, A71L and Q58E mutations of HIV-1 protease to assess amprenavir susceptibility, as evidenced by printouts of query results from the Stanford University HIV Drug Resistance Database. However, Applicants respectfully submit that Kempf *et al.* itself teaches neither these mutations nor their use in accessing amprenavir resistance. Kempf *et al.* purports to disclose the identification of genotypic changes in HIV protease with reduced susceptibility to lopinavir. The genotypic changes identified in Kempf *et al.* do not include the L33F, K43T, A71L and Q58E mutations. *See* Kempf *et al.*, Table 3. In addition, Kempf *et al.* specifically states that the correlation between susceptibility to lopinavir and amprenavir was relatively low. *See* Kempf *et al.*, page 7467, left column, first paragraph. As such, Kempf *et al.* does not teach a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with AP. Nor does Kempf *et al.* teach the presence of any particular mutation of HIV protease indicates that HIV-1 has an increased likelihood of having reduced susceptibility to treatment with amprenavir.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 14, 17, 20, 36 and 42 as being anticipated by Kempf *et al.* under 35 U.S.C. § 102(b) be withdrawn.

F. The Rejection of Claims 1, 12, 14, 15, 16, 18, 19, 25, 29, 30, 32-37, 39, 40 and 42 over Beerenwinkel *et al.*

Claims 1, 12, 14, 15, 16, 18, 19, 25, 29, 30, 32-37, 39, 40 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Beerenwinkel *et al.*, 2002, Accession No. AAK32197 ("Beerenwinkel *et al.*"). Applicants respectfully traverse.

The Patent Office alleges that Beerenwinkel *et al.* teaches the use of L33F, G48M, I54A, C95F, P79L and T91I mutations of HIV-1 protease to assess amprenavir susceptibility. The Patent Office uses the printouts of query results from the Stanford University HIV Drug Resistance Database to show that Beerenwinkel *et al.* teaches these mutations and their association with amprenavir resistance. However, Applicants respectfully submit that

Beerenwinkel *et al.* itself teaches neither these mutations nor their use in accessing amprenavir resistance. Applicants respectfully request the Patent Office cite the page and line number of Beerenwinkel *et al.* that teaches the use of L33F, G48M, I54A, C95F, P79L and T91I mutations of HIV-1 protease to assess amprenavir susceptibility.

Applicants respectfully submit that Beerenwinkel *et al.* does not anticipate amended Claims 1, 12, 14, 15, 16, 18, 19, 25, 29, 30, 32-37, 39, 40 and 42 because Beerenwinkel *et al.* does not teach each and every element of Claims 1, 12, 14, 15, 16, 18, 19, 25, 29, 30, 32-37, 39, 40 and 42 as presently amended. For example, Beerenwinkel *et al.* does not teach or suggest the recited mutations. Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 14, 15, 16, 18, 19, 25, 29, 30, 32-37, 39, 40 and 42 as being anticipated by Beerenwinkel *et al.* under 35 U.S.C. § 102(b) be withdrawn.

G. The Rejection of Claims 1, 12, 14, 15, 26-27, 29, 34, 36-37, 39-40 and 42 over Pausen *et al.*

Claims 1, 12, 14, 15, 26-27, 29, 34, 36-37, 39-40 and 42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pausen *et al.*, 2000, *ANTIVIRAL THERAPY* 6(Supplement):51-52 ("Pausen *et al.*"). The Patent Office alleges that Pausen *et al.* teaches L33F mutation of HIV-1 protease can be used to assess amprenavir susceptibility. Although Applicants do not agree with this rejection, to expedite the prosecution of the instant application, Applicants have amended Claims 1 and 12 by deleting the amino acid position 33 from the claim. Applicants respectfully submit that the rejection of Claims 1, 12, 14, 15, 26-27, 29, 34, 36-37, 39-40 and 42 is obviated in view of the claim amendments as Pausen *et al.* does not teach each and every element of the invention as presently claimed. Therefore, Pausen *et al.* cannot anticipate Claims 1, 12, 15, 26-27, 29, 34, 36-37, 39-40 and 42 as presently pending. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990).

Accordingly, Applicants respectfully request that the rejection of Claims 1, 12, 14, 15, 26-27, 29, 34, 36-37, 39-40 and 42 as being anticipated by Pausen *et al.* under 35 U.S.C. § 102(b) be withdrawn.

IV. THE REJECTION OF CLAIM 1, 32 AND 33 UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1, 32 and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 32 and 33 have been canceled. The rejection of Claims 32-33 is moot in view of the cancellation of the claims.

Claim 1 includes a negative limitation "with the proviso that said mutation is not I54V or V82V." The Patent Office asserts that the negative limitations are not supported by the specification as originally filed. Applicants respectfully submit that the generic disclosure of mutations of HIV protease associated with amprenavir resistance and the extensive examples provided in the instant application provides sufficient written description support for excluding the mutations of I54V and V82V, two species within the genus of the mutations. Support for the proposition that claims can be properly amended to exclude a particular species of a genus can be found in § 2173.05(i) of M.P.E.P, which states that "If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. *See In re Johnson*, 558 F.2d 1008, 1019, 194 U.S.P.Q. 187 (C.C.P.A. 1977), ("[the] specification, having described the whole, necessarily described the part remaining."). *See* also *Ex parte Grasselli*, 231 U.S.P.Q. 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984)."

In the instant case, the mutations I54V and V82A were originally described in the application as filed, for example, at page 44, lines 9-10, and in Tables 1-2. Accordingly, the amendment excluding these mutations is fully supported by the application as filed and presents no new matter.

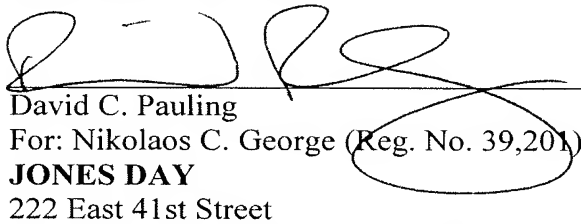
In view of applicable case law and the support provided in the specification, Applicants respectfully request that the rejection of Claims 1, 32 and 33, under 35 U.S.C. § 112, first paragraph be withdrawn

CONCLUSION

Pursuant to 37 C.F.R. §1.136 (a)(3), the Commissioner is authorized to charge all required fees, or credit any overpayment, to Jones Day Deposit Account No. 50-3013 (949677-999063).

Respectfully submitted,

Date: December 14, 2007



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